Application No. 09/537,118 Docket No.: N9810.0007/P007 Amendment dated July 2, 2008

Reply to Office Action of January 3, 2008

AMENDMENTS TO THE CLAIMS

Claims 1-26 canceled.

27. (Previously presented) The method of claim 80, wherein the spray composition further comprises a flavoring agent in the amount of between 0.1 and 10 percent by weight of the total composition.

- 28. (Previously presented) The method of claim 27, wherein the polar solvent is present in an amount between 27 and 98 percent by weight of the total composition, the active compound is present in an amount between 0.005 and 55 percent by weight of the total composition, and the flavoring agent is present in an amount between 0.5 and 8 percent by weight of the total composition.
- 29. (Previously presented) The method of claim 80, wherein the polar solvent is present in an amount between 59 and 97 percent by weight of the total composition, the active compound is present in an amount between 0.01 and 40 percent by weight of the total composition, and the flavoring agent is present in an amount between 0.75 and 7.5 percent by weight of the total composition.
- 30. (Previously presented) The method of claim 80, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a molecular weight between 400 and 1000, C₂ to C₈ mono- and poly-alcohols or C₇ to C₁₈ alcohols of linear or branched configuration.
- 31. (Previously presented) The method of claim 80, wherein the polar solvent comprises aqueous polyethylene glycol.
- 32. (Previously presented) The method of claim 80, wherein the polar solvent comprises aqueous ethanol.
 - 33. (Canceled).

Application No. 09/537,118

Amendment dated July 2, 2008

Reply to Office Action of January 3, 2008

Docket No.: N9810.0007/P007

34. (Previously presented) The method of claim 80, wherein the flavoring agent comprises a synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners or mixture thereof.

Claims 35 - 53 canceled.

- 54. (Previously presented) The method of claim 81, further comprising a flavoring agent in the amount between 0.1 and 10 percent by weight of the total composition.
- 55. (Previously presented) The method of claim 54, wherein the non-polar solvent is present in an amount between 69 and 99 percent by weight of the total composition, the active compound is clozepine in an amount from between 0.5 and 30 percent by weight of the total composition, and the flavoring agent is present in an amount between 0.1 and 5 percent by weight of the total composition.
 - 56. (Canceled).
- 57. (Previously presented) The method of claim 54, wherein the flavoring agent compromises a synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweetener or a mixture thereof.
- 58. (Previously presented) The method of claim 81, wherein the solvent is selected from the group consisting of (C_2-C_{24}) fatty acid (C_2-C_6) esters, C_7-C_{18} hydrocarbons of linear or branched configuration, and C_2-C_6 alkanoyl esters or triglycerides of a C_2-C_6 carboxylic acid.
- 59. (Previously presented) The method of claim 81, wherein the solvent comprises one or more fatty acid esters.

Claims 60 - 79 canceled.

80. (Currently amended) A method for administering an effective amount of a pharmacologically active compound to a mammal to provide transmucosal absorption of a pharmacologically effective amount of the active compound through the oral mucosa of the mammal to the systemic circulatory system of the mammal, comprising:

spraying the oral mucosa of the mammal with a propellant free buccal spray composition, containing a pharmacologically active compound dissolved in a pharmacologically acceptable solvent, comprising in weight percent of the composition:

an active compound in an amount of between 0.001 and 60 percent selected from the group consisting of a benzodiazepine, a clozapine, phenytoin or a pharmaceutically acceptable salt thereof; and

a polar or a non-polar solvent in an amount between 30 and 99.69 percent,

wherein a therapeutically pharmacologically effective amount of the active compound is absorbed through the oral mucosa of the mammal to the mammal's systemic circulatory system; and

wherein a therapeutic effect of the active compound administered by the act of spraying is achieved with a first amount of the active compound, the first amount being less than a second amount of the active compound necessary to achieve the therapeutic effect when passed through a gastrointestinal tract of the mammal.

81. (Currently amended) A method for administering an effective amount of a pharmacologically active compound to a mammal to provide transmucosal absorption of a pharmacologically effective amount of the active compound through the oral mucosa of the mammal to the systemic circulatory system of the mammal, comprising:

spraying the oral mucosa of the mammal with a propellant free buccal spray composition, containing a pharmacologically active compound dissolved in a pharmacologically acceptable solvent, comprising in weight percent of the composition:

Reply to Office Action of January 3, 2008

an active compound in an amount between 0.005 and 55 percent selected from the group consisting of a benzodiazepine, a clozapine, phenytoin or a pharmaceutically acceptable salt thereof; and

a polar or a non-polar solvent in an amount between 30 and 99.69 percent,

wherein a therapeutically pharmacologically effective amount of the active compound is absorbed through the oral mucosa of the mammal to the mammal's systemic circulatory system; and

wherein a period of time for onset of a therapeutic effect of an amount of the active compound administered by the act of spraying is less than a period of time for onset of the therapeutic effect for the amount of the active compound when passed through a gastrointestinal tract of the mammal.

82. (Canceled).